

DETAILED ACTION

This application is a 371 (national stage application) of PCT/FR04/01628, filed on 6/25/2004. Priority was acknowledged in the previous office action.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/2011 has been entered.

Declaration Pursuant to 37 CFR § 1.132

2. The declaration under 37 CFR 1.132 filed 1/12/2011 is sufficient to overcome the rejection of claims 27-28 and 35-38, under 35 USC 103(a) based upon Todd, in view of Schwartz et. al. The Applicants have provided unexpected results for the combination of olanzapine and BF2649, which has the effect of reducing hunger levels lower than the placebo effect. The rejection under 35 USC 103(a) as being unpatentable over Todd, in view of Schwartz et. al., is withdrawn.

Terminal Disclaimer

3. The terminal disclaimer filed on 1/12/2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 11/815736 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Remarks

4. Claims 27-28, 35-38, and 41-64 are pending as of the reply filed on 1/12/2011; claims 1-26, 29-34, and 39-40 have been cancelled by the Applicants, and claims 63-64 have been newly added.

The rejection for obviousness type double patenting over the claims of co-pending application 11/815736 is withdrawn in consideration of the acceptance of the terminal disclaimer filed on 1/12/2011.

The rejection under 35 USC 103(a) as being unpatentable over Todd, in view of Schwartz et. al. is withdrawn in consideration of the claim amendments filed on 1/12/2011, Applicants' arguments, and the declaration submitted under 37 CFR § 1.132 by Dr. Jean-Charles Schwartz. The declaration shows that the pharmaceutical composition comprised of therapeutically effective amounts of olanzapine and BF2649 was more effective than placebo in reducing feelings of hunger. The claimed composition comprised of olanzapine and BF2649 is therefore found to be non-obvious over the prior art. Claims 27-28, 35-38, and 63-64 are free of the prior art. An examiner's amendment and statement of reasons for allowance are disclosed below.

Examiner's Amendment

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William Ferrell on 10/18/2011.

Please amend the claims accordingly:

6. Delete claims 41-62.

Statement of Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance: there is no prior art which teaches or suggests the claimed composition comprised of therapeutically effective amounts of olanzapine and BF2649. The closest prior art is Todd, WO 00/74784, and Schwartz et. al., US Patent No. 7,138,416 (both of prior record). Todd teaches olanzapine as an antipsychotic which causes side effects such as weight gain, and that the side effects are reduced by co-administration of olanzapine with an H₂ antagonist. Schwartz et. al. teaches that BF2649 is effective in treating obesity and administration with anti-psychotics to reduce side effects. However, neither reference teaches or suggests the unexpected benefit associated with the combination of olanzapine and the

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histamine H₃ antagonist, BF2649. The composition of claims 27-28, 35-38, 63, and 64 is therefore novel and non-obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. Claims 27-28, 35-38, 63, and 64 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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S.P.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627